K113267

DEC - 2 2011

510(k) Summary

1. Applicant Name and Address

CooperVision, Inc.
6150 Stoneridge Mall Drive
Suite 370
Pleasanton CA 94588

2. Contact

Gwen Sharp
Regulatory Affairs
(925) 621-2457
gsharp@coopervision.com

3. Date Prepared

November 3, 2011

4. Device Identification

Trade Name:	Biomedics 52 Biomedics 52 1-Day
Common Name:	Soft Contact Lens
Classification Name:	Soft (hydrophilic) Contact Lens – Daily Wear; Disposable
Device Classification:	Class II (21 CFR 886.5925)
FDA Material Class:	FDA Group IV, High Water, Ionic Polymer
Product Code:	MVN, LPL

5. Device Description

The Biomedics 52 *(ocufilcon B)* soft contact lens is a Group IV, daily wear silicone hydrogel contact lens that is not surface treated and is characterized by a high oxygen permeability (Dk). The lens material, *ocufilcon B*, is composed of polymerized material of HEMA and cross linked with other monomers, incorporating phthalocyanine blue as an integrated, handling tint. A UV blocker is added to reduce the amount of ultraviolet light transmitted into the eye. The lenses are manufactured in spherical and toric configurations. The Biomedics 52 *(ocufilcon B)* Soft (hydrophilic) contact lenses are a hemispherical shell. The physical properties and available dimensions are unchanged from predicate 510(k)s.

6. Intended Use

SPHERICAL
Biomedics 52 *(ocufilcon B)* Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 2.00 diopters that does not interfere with visual acuity.

TORIC
Biomedics 52 *(ocufilcon B)* Soft (Hydrophilic) UV Blocking Contact lenses are indicated for the correction of visual acuity in persons with non-diseased eyes that are myopic (nearsighted) or hyperopic (farsighted) and may exhibit refractive astigmatism of 10.00 diopters.

The lens may be prescribed for Daily Wear in not-aphakic persons. The eyecare practitioner may prescribe the contact lens for either single-use disposable wear or for frequent replacement wear, with cleaning, disinfection, and scheduled replacement. When prescribed for single-use disposable wear the lens is to be discarded after each removal. When prescribed for frequent replacement wear, the contact lens may be disinfected using a chemical (not heat) disinfecting system.

The Biomedics *(ocufilcon B)* Soft (Hydrophilic) UV Blocking Contact Lenses help protect against transmission of harmful UV radiation to the cornea and into the eye.

7. Predicate Device(s)

- Biomedics 52 *(ocufilcon B)* Soft (Hydrophilic) UV Blocker Daily Wear Contact Lens (K003136) January 16, 2001
- Biomedics 52 1-Day *(ocufilcon B)* Soft (Hydrophilic) UV Blocking Contact Lens for Daily Wear (K020389) June 4, 2002

8. Characteristics of Substantial Equivalence

The soft contact lenses have the following similarities to the predicate lens that previously received 510(k) clearance:

- have the same indicated use,
- incorporate the same design,
- incorporate the same materials,
- have the same shelf life, and
- are packaged and sterilized using the same materials and processes.

The modifications to the stability/shelf life protocol include an alternate test method for package integrity and adjusted storage temperatures for the packaged products that will be tested using alternate package integrity test method.

In summary, the *ocufilcon B* soft contact lenses described in this submission are substantially equivalent to the predicate device.

9. Physiochemical Studies

Results from physical, optical and chemical properties were not required as support for this modification to shelf life protocol. Change will not affect physicochemical properties of the lenses.

10. Toxicology Studies

Results from in-vivo and in-vitro studies were not required as support for this modification to shelf life protocol. Change will not affect lenses ability to remain non-toxic and biocompatible with the ocular environment.

11. Conclusions of Non-Clinical Tests Performed:

- **Physiochemical:**

  The physical, optical and chemical properties of this lens remain unchanged from the unmodified device, and are within established specifications for the lenses.

- **Toxicology:**

  Results from in-vivo and in-vitro studies originally conducted remain valid and verify that the lenses remain non-toxic and are biocompatible with the ocular environment.

12. Clinical Studies

The technical characteristics, formulation, manufacturing, and sterilization processes of this lens are not changing and therefore are equivalent to *ocufilcon B* soft contact lenses currently marketed by CooperVision, therefore no clinical data is required.

13. Conclusions

Based on no change to material, no change to manufacturing methods, no change to lens parameters and no change to indicated use, the *ocufilcon B* soft contact lens described in this document are substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CooperVision, Inc.
c/o Ms. Gwen Sharp
Global Regulatory Affairs
6150 Stoneridge Mall Road
Suite 370
Pleasanton, CA 94588

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Re: K113267
Trade/Device Name: Biomedics 52 (ocufilcon B) Soft (Hydrophilic) UV Blocker Daily Wear Contact Lens
Biomedics 52 1-Day (ocufilcon B) Soft (Hydrophilic) UV Blocking Contact Lens for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) contact lenses
Regulatory Class: Class II
Product Code: LPL and MVN
Dated: November 3, 2011
Received: November 4, 2011

Dear Ms. Sharp:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K113267

Device Name: Biomedics 52 *(ocufilcon B)* Soft (Hydrophilic) UV Blocker Daily Wear Contact Lens
Biomedics 52 1-Day *(ocufilcon B)* Soft (Hydrophilic) UV Blocking Contact Lens for Daily Wear

Indications for Use:

SPHERICAL
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Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear, Nose and Throat Devices

510(k) Number K113267